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EXAMINER

DEES, NIKKI H

ART UNIT	PAPER NUMBER
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1794

NOTIFICATION DATE	DELIVERY MODE
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05/05/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com

Office Action Summary	Application No. 10/528,927	Applicant(s) ANDERSEN ET AL.	
	Examiner Nikki H. Dees	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14-26, 28-31 and 33-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14-26, 28-31 and 33-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>26 Feb. 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 26, 2009, has been entered.

2. Claims 1-9, 14-26, 28-31 and 33-57 are currently pending in the Application. The previous 103 rejections over Goldberg et al. have been withdrawn in view of Applicant's arguments. The previous double patenting rejections have been amended as indicated below.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 50 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method as described in the specification,

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does not reasonably provide enablement for the method as claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to carry out the invention commensurate in scope with this claim.

4. One skilled in the art cannot carry out the method commensurate in scope with claim 50. The specification teaches specific processing steps for increasing the molecular weight and forming the polymer. The claim does not have any limitation to what polymer is used, how the molecular weight of the polymer is increased, or what molecular weight is allowed. Also, in order to increase the robustness of chewing gum, a chewing gum has to be formed first. There is no step to forming the chewing gum.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-9 and 50-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1-9 and 50-57 are indefinite for claiming the invention in terms of physical properties rather than the chemical or structural features that produce said properties.

Ex parte Slob, 157 USPQ 172, states, "Claims merely setting forth physical characteristics desired in an article, and not setting forth specific composition which would meet such characteristics, are invalid as vague, indefinite, and functional since they cover any conceivable combination of ingredients either presently existing or which might be discovered in the future and which would impart said desired characteristics."

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Also, "it is necessary that the product be described with sufficient particularity that it can be identified so that one can determine what will and will not infringe." *Benger Labs, Ltd v. R.K. Laros Co.*, 135 USPQ 11, *In re Bridgeford* 149 USPQ 55, *Locklin et al. v. Switzer Bros., Inc.*, 131 USPQ 294. Furthermore, "Reciting the physical and chemical characteristics of the claimed product will not suffice where it is not certain that a sufficient number of characteristics have been recited that the claim reads only on the particular compound which applicant has invented." *Ex parte Siddiqui*, 156 USPQ 426, *Ex parte Davission et al.*, 133 USPQ 400, *Ex parte Fox*, 128 USPQ 157.

8. Claim 1 is further considered to be indefinite as claim 1 claims a chewing gum "substantially free" of non-biodegradable polymers. It is unclear how much non-biodegradable polymer the chewing gum may contain to be considered "substantially free" of said polymers.

9. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the molecular weight of the polymer is increased and how the chewing gum is formed.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-9, 14-18, 20-25, 28-30, 33-39, and 49-57 are rejected under 35

U.S.C. 102(b) as being anticipated by Grijpma et al. (5,672,367).

12. Regarding claims 1 and 49, Grijpma et al. teach a chewing gum comprising at least one biodegradable polymer (Abstract). The chewing gum is substantially free of non-biodegradable polymers (col. 1 lines 22-24), and comprises at least one softener (col. 2 lines 48-49; Example 2).

13. Regarding claims 14-18 and 20, Grijpma et al. teach known food flavors for use in their invention in the amount ranging from 0.1 to 10% by weight (col. 2 lines 63-65).

14. Regarding claims 21-25, Grijpma et al. teach sweeteners for use in their invention including bulk sweeteners and high intensity sweeteners such as aspartame (col. 2 lines 50-62).

15. Regarding claims 28 and 29, Grijpma et al. teach softeners/emulsifiers for use in their invention including lecithin. Softeners are added in an amount from 0.5 to 15 % by weight (col. 2 lines 48-50).

16. Regarding claim 30, Grijpma et al. state that their chewing gum may contain medicinal components (claim 11).

17. Regarding claims 33-36, the biodegradable polymers of Grijpma et al. are produced by the polymerization of cyclic esters including lactide, trimethylene carbonate and δ -valerolactone (col. 1 lines 50-55).

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18. Regarding claims 37-39, the chewing gum of Grijpma et al. comprises filler in an amount of less than 50 % by weight (col. 2 lines 35-37). The chewing gum may also comprise coloring agents (col. 3 line 3).

19. Grijpma et al. are silent as to the number average molecular weight and polydispersity of the polymers used in their invention.

20. However, absent any convincing arguments or evidence to the contrary, one of ordinary skill in the art at the time the invention was made would have had the reasonable expectation that, though not reported by Grijpma et al., the number average molecular weight of the biodegradable polymers for use in the invention of Grijpma would have fallen within the ranges as claimed by Applicant. Grijpma et al. are using the biodegradable polymers to entirely replace conventional chewing gum polymers, as are Applicants, and are combining the biodegradable polymers with conventional chewing gum ingredients. Further, Grijpma et al. state that their chewing gum product “provided a chew feel strongly resembling that of a conventional chewing gum.” (col. 4 lines 13-14). The burden falls to Applicant to show that the biodegradable polymers taught by Grijpma et al. for use in chewing gums do not fall within the number average molecular weight ranges and polydispersity ranges as claimed by Applicants. The burden also falls to Applicant to show that the chewing gum of Grijpma et al. does not have the “increased robustness” as claimed by Applicant.

21. Claims 1-9, 14-26, 28, 29, 33, 36-39, and 49-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Li (WO 00/19837).

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22. Regarding claims 1 and 49, Li teaches a chewing gum comprising at least one biodegradable polymer (p. 2 lines 15-16). The chewing gum is substantially free of non-biodegradable polymers (p. 7 lines 15-19), and comprises at least one softener (p. 7 lines 1-2).

23. Regarding claims 14-18, 20, and 39, Li teaches known food flavors and colorants for use in his invention. Flavorants are preferably present in an amount ranging from about 0.5 to 3 wt % (p. 12 lines 21-31).

24. Regarding claims 21-26, Li teaches sweeteners for use in his invention including bulk sweeteners and high intensity sweeteners such as aspartame. The bulk sweeteners may be present in an amount ranging from 5 to 90 wt %. The amount of high intensity sweetener taught for use in the invention is less than 1% (p. 11 lines 20-24; p. 12 lines 1-20).

25. Regarding claims 28 and 29, Li teaches softeners/emulsifiers for use in their invention including partially hydrogenated vegetable oils (p. 9 lines 1-5) and lecithin. Li teaches the softeners for use in an amount ranging from 0.5 to 25 wt % (p. 11 lines 25-27).

26. Regarding claims 33 and 36, the biodegradable polymers of Li comprise poly(D,L-lactide acid-co-glycolide) and poly(D,L-lactide acid) (p. 2 lines 15-17).

27. Regarding claims 37 and 38, the chewing gum of Li comprises filler in an amount of less than 50 % by weight (col. 2 lines 35-37).

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28. Li is silent as to the number average molecular weight and polydispersity of the polymers used in their invention, as well as to a method for increasing the robustness of the chewing gum.

29. However, Li teaches the molecular weight of the polymers for use in his invention. Though he does not teach the number average molecular weight, absent any convincing arguments or evidence to the contrary, one of ordinary skill in the art at the time the invention was made would have had the reasonable expectation that, though not reported by Li, the number average molecular weight of the biodegradable polymers for use in the invention of Li would have fallen within the ranges as claimed by Applicant. Li is using the biodegradable polymers to entirely replace conventional chewing gum polymers, as are Applicants, and are combining the biodegradable polymers with conventional chewing gum ingredients.

30. The burden falls to Applicant to show that the biodegradable polymers taught by Li for use in chewing gums do not fall within the number average molecular weight ranges and polydispersity ranges as claimed by Applicants. The burden also falls to Applicant to show that the chewing gum of Li does not have the "increased robustness" as claimed by Applicant.

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

32. Claims 19, 26, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grijpma et al. (5,672,367).

33. Regarding claim 1, Grijpma et al. teach a chewing gum comprising at least one biodegradable polymer as detailed above

34. Regarding claim 19, Grijpma et al. teach known food flavors for use in their invention in the amount ranging from 0.1 to 10% by weight (col. 2 lines 63-65). The selection of any particular flavor, including acids, for use in the chewing gum would have been an obvious matter of choice of the skilled artisan to impart the chewing gum with the flavor desired.

35. Regarding claim 26, Grijpma et al. teach sweeteners for use in their invention including high intensity sweeteners such as aspartame (col. 2 lines 50-62). Grijpma et al. do not specifically state the amount of high intensity sweetener that may be used in their invention. However, as with flavoring, it would have been well within the abilities of one to determine the appropriate amount of sweetener to add to impart the gum composition with the desired sweetness.

36. Regarding claim 31, Grijpma et al. state that their chewing gum may contain medicinal components (claim 11). One of ordinary skill would have found it obvious to add any of the multitude of active ingredients as claimed by Applicants as actives are known to be added to chewing gums if desired.

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37. Claims 40-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grijpma et al. (5,672,367) as applied to claim 1 above in view of Zyck et al. (US 2001/0021373 A1).

38. Grijpma et al. teach their chewing gum product in the form of rolled, extruded, or formed into pellets (col. 3 lines 8-12).

39. Grijpma et al. are silent as to further coating the chewing gum product.

40. Zyck et al. teach a coated chewing gum product where the coating is sugarless and may comprise xylitol, sorbitol, gelatin, flavors, and other common conventional coating agents [0056].

41. Regarding claim 47, Zyck et al. primarily teach hard coating of gum cores. However, one of ordinary skill in the art at the time the invention was made would have found it an obvious matter of choice to provide the gum with a soft coating depending on the gum type being produced. One of ordinary skill producing the invention of Grijpma et al. in stick form would have found it obvious to provide a soft coating. This would have been a routine operation for one of ordinary skill in the art.

42. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 00/19837).

43. Regarding claim 1, Li teaches a chewing gum comprising at least one biodegradable polymer as detailed above.

44. Regarding claim 19, Li teaches known food flavors and colorants for use in his invention. Flavorants are preferably present in an amount ranging from about 0.5 to 3

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wt % (p. 12 lines 21-31). The selection of any particular flavor, including acids, for use in the chewing gum would have been an obvious matter of choice of the skilled artisan to impart the chewing gum with the flavor desired.

45. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 00/19837) in view of Grijpma et al. (5,672,367).

46. Li teaches a chewing gum according to claim 1, as detailed above.

47. Li is silent as to his chewing gum comprising active ingredients.

48. Grijpma et al. state that their chewing gum may contain medicinal components (claim 11).

49. One of ordinary skill wishing to provide active ingredients in the chewing gum of Li would have found it obvious to add any of the multitude of active ingredients as claimed by Applicants as actives are known to be added to chewing gums if desired, as taught by Grijpma et al.

50. Claims 40-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 00/19837) as applied to claim 1 above in view of Zyck et al. (US 2001/0021373 A1).

51. Li teaches his chewing gum product in the form of sticks, chunks, or pellets (p. 13 lines 5-6).

52. Li is silent as to further coating his chewing gum product.

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53. Zyck et al. teach a coated chewing gum product where the coating is sugarless and may comprise xylitol, sorbitol, gelatin, flavors, and other common conventional coating agents [0056].

54. Regarding claim 47, Zyck et al. primarily teach hard coating of gum cores.

However, one of ordinary skill in the art at the time the invention was made would have found it an obvious matter of choice to provide the gum with a soft coating depending on the gum type being produced. For example, Zyck et al. teach coating of pellets [0055].

One of ordinary skill producing the invention of Li in stick form would have found it obvious to provide a soft coating. This would have been a routine operation for one of ordinary skill in the art.

Double Patenting

55. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

56. Claims 1-9, 14-26, 28-31 and 33-57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-62 of U.S. Patent No. 7,507,427. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims to a coated chewing gum comprising biodegradable polymers are considered obvious over conflicting claims to specific amounts by weight of the chewing gum center comprising an environmentally degradable chewing gum center and an outer coating.

57. Claims 1-9, 14-26, 28-31 and 33-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over: claims 1-6, 8, 10-13, and 15-66 of copending Application No. 10/528,926; claims 1-24, 26-43, and 45-64 of copending Application No. 10/528,930; claims 1-20, 22, 23, 25, 26, 28-30 and 36-42 of copending Application No. 10/529,133; and claims 1, 3-7, and 9-55 of copending Application No. 10/529,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because the chewing gum claimed in the claims of each of said applications is merely an obvious variation of the chewing gum claimed by applicant in the instant application. Application 10/528,926 claims a chewing gum comprising biodegradable polymers in terms of T_g . Application 10/528,930 claims a chewing gum comprising biodegradable polymers polymerized from specific monomers. Application 10/529,133 claims a chewing gum comprising

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biodegradable polymers having a Mn overlapping with that of the instant application.

Application 110/529,137 claims a chewing gum comprising biodegradable polymers and conventional chewing gum ingredients. The copending claims to different properties of the polymers (e.g. T_g) or the specific monomers from which the polymers are produced are all considered to be obvious variations of the instant claims as one of ordinary skill would have found it obvious to alter these properties depending on the texture desired in the final chewing gum product.

58. These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Response to Arguments

59. Applicant's arguments filed February 26, 2009, with respect to claims 1-57 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday from 10:30 AM to 8:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks, can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/N. H. D./
Examiner, Art Unit 1794
/Lien T Tran/
Primary Examiner, Art Unit 1794

Nikki H. Dees
Examiner
Art Unit 1794